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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/524,422

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Randall W. Nelson

530-006

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09/25/2002

SNELL & WILMER
ONE ARIZONA CENTER
400 EAST VAN BUREN
PHOENIX, AZ 850040001

EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/25/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,422

Applicant(s)

NELSON, RANDALL W.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the claims

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 48-69 have been renumbered 1-22 respectively. The Transmittal letter states that a 50 page specification was transmitted and 22 claims were submitted. However, applicant submitted claims 48-69. There were no previous claims 1-47 submitted. Therefore claims 48-69 have been renumbered appropriately.

Election/Restrictions

Applicant's election without traverse of Group I, claims 48-55(renumbered 1-8 respectively) in Paper No. 4 is acknowledged.

Specification

The use of the trademark Lumonics HY 400 has been noted in this application on page 41. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because of the following informalities:

On page 4, line 19 of the specification between the disclosure "field bimolecular" insert --of--.

On page 5, line 26 "quantification" should be --quantitative--.

On page 6, lines 22-23 it is recommended to delete [and is herein incorporated by reference].

On page 17, line 12 it is recommended to insert --,-- after the term nylon.

On page 36 at the end of the second paragraph it is recommended to insert --,--.

On page 46 at the end of the last paragraph it is recommended to insert --,--.

Appropriate correction is required.

Claim Objections

Claim 6 is objected to because of the following informalities: Claim 6 depends from claim 5 and thus is a duplicate claim. Perhaps applicant intends for claim 6 to depend from claim 3. Claim 6 has not been treated on art. However, if applicant should amend the claim any art rejection will be made FINAL.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 2 a recitation of "affinity reagent is bound to a filter element", but there is no support for this limitation disclosed anywhere in the specification. Further, claims 5-8 recite the limitations that the filter element is securely fixed to the tip and that the filter element is removably fixed within the tip. On pages 40-41 applicant disclose beads having affinity reagent immobilized thereon and Applicant discloses slurried affinity reagent incubated with specimen and internal reference. Applicant also disclosed the affinity reagent contains myotoxin a affinity bound to the retain anti-myotoxin a, which was physically separated from the specimen by forcing the volume through the backside of a P-10, 10 μ L filter pipette tip thereby retaining the affinity reagent on the filter. The applicant does not disclose a filter element to which the affinity reagent is bound. There is no description in the specification disclosing that the affinity reagent is bound to a filter element. Nor is there a description in the specification disclosing that the filter element is securely fixed to the tip or that the filter element is removably fixed to the tip.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rosman et al (US Patent 5,079,170).

Rosman et al disclose a tip comprising a filter matrix and an immunologically active substance (affinity reagent) such as antibodies or antigens (col 6, lines 10-20).

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wainwright et al (US Patent 5,171,537).

Wainwright et al disclose a micropipette tip having an affinity reagent present within the tip (col 2, lines 17-31).

4. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Raybuck et al (US Patent 5,833,927).

Raybuck et al disclose a pipette tip having an open rearward end adapted to be fitted on a micropipette for drawing fluid into the pipette tip (abstract). Raybuck et al

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disclose a porous membrane (filter element) may be mounted at or adjacent the forward end or may be secured to the forward end of the pipette tip by means of a securing collar. Raybuck et al also disclose that the membrane (filter element) may be made peelable from the pipette tip for subsequent processing. Raybuck et also disclose that an antibody or other specific binding species (affinity reagents) can be immobilized on the membrane by a variety of chemical and physical means (col 6, lines 1-67, See also figure 5).

5. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Bieber et al (Mass Spectrometric Immunoassay, Anal. Chem. 1995, 67, 1153-1158).

Bieber et al disclose a filter pipette tip having an affinity reagent present within the tip (p. 1154 experimental section, see also figure 1).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieber et al in view of Raybuck et al (US Patent 5,833,927).

See above for teachings of Bieber et al.

Bieber et al differ from the instant invention in failing to disclose the affinity reagent is bound to a filter element.

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Raybuck et al disclose a micropipette tip comprising a porous membrane (filter element which has specific binding partners (affinity reagent) bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate bound affinity reagent such as taught by Raybuck et al into the device of Bieber et al because Raybuck et al shows that this provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

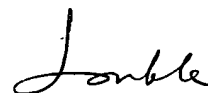
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
September 23, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/23/02